REMARKS

Status of the Claims

Claims 10-14 and 21-30 are now pending in this application. Claim 10 is independent. Claims 1-9 and 15-21 are canceled, and claims 10-11 and 14 are herein amended. Support for the amendments of the claims can at least be found at page 3, lines 8-13 of the specification as filed. No new matter is added. Thus, reconsideration of this application, as amended, is respectfully requested.

Reasons for Entry of Amendments

At the outset, it is respectfully requested that this Amendment be entered into the Official File in view of the fact that the amendments to the claims automatically place the application in condition for allowance.

In the alternative, if the Examiner does not agree that this application is in condition for allowance, it is respectfully requested that this Amendment be entered for the purpose of appeal. This Amendment reduces the issues on appeal by placing the claims in compliance with 35 U.S.C. §112, second paragraph, 35 U.S.C. §102(b) and 35 U.S.C. §103(a). This Amendment was not presented at an earlier date in view of the fact that Applicants did not fully appreciate the Examiner's position until the Final Office Action was reviewed.

Priority under 35 U.S.C. § 119

Applicants thank the Examiner for acknowledging Applicants' claim for foreign priority under 35 U.S.C. § 119, and receipt of the certified priority document.

Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 10-14 and 21-30 stand rejected under 35 U.S.C. § 112, second paragraph. This rejection is respectfully traversed.

The Examiner has set forth certain instances wherein the claim language lacks antecedent basis or is not clearly understood.

In response, Applicants have amended independent claim 10 to correct each of the deficiencies specifically pointed out by the Examiner. Applicants respectfully submit that the claims, as amended, particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully submit that the Amendments to claim 10 are non-narrowing claim amendments. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

With regard to dependent claims 11-14 and 21-30, Applicants submit that claims 11-14 and 21-30 depend, either directly or indirectly, from independent claim 10 which is allowable for the reasons set forth above, and therefore claims 11-14 and 21-30 are allowable based on their dependence from claim 10. Thus, reconsideration and allowance thereof are respectfully requested.

Rejection under 35 U.S.C. § 102(b)

Claims 10-14 and 21-30 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Moghaddam et al. '718, U.S. Patent No. 5,972,718, ("Moghaddam"). This rejection is respectfully traversed.

According to the Examiner, this rejection is being maintained for the reasons stated on page 10 of the outstanding Office Action. Specifically, the Examiner refers Applicants to the disclosure at col. 11, lines 48-56 of Moghaddam '718, which appears to disclose red blood cells or other particles *coated* with antibodies. Thus, the Examiner insists that Moghaddam '718 discloses a species that anticipates the claimed genus.

Legal Standard for Determining Anticipation

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001).

Distinctions over the Cited References

Applicants respectfully submit that the method steps of Moghaddam differ from the method steps of the present invention. Specifically, Moghaddam teaches a detection method of HITP antibodies involving the following steps: (1) incubation of a polymer surfactant, such as polyvinyl sulfate, with human platelet factor 4; (2) attachment of the polymer surfactant/human platelet 4 complex to a solid support, such as a microtiter plate; (3) addition of a stabilizing agent; (4) addition of a test sample (in this case, a patient with HITP-generated antibody); and (5) detection of antibody bound to the target polymer surfactant/human platelet 4 complex, *see* Moghaddam, column 7, lines 54-65.

In contrast, claim 10 (and claims 11-14, 21-30 which depend therefrom) describes an immunoassay involving the following steps: (1) mixing a test sample with a polymer surfactant (agent), and (2) subjecting a mixture to antigen-antibody immunoagglutination reaction with sensitized particles or with an antiserum to form a reacted mixture. As indicated, the teachings of Moghaddam differ from the present invention because the detection step occurs ***after*** the polymer surfactant and human platelet 4 complex is formed.

In addition, Moghaddam discloses an alternative embodiment whereby sensitized particles (latex particles) can be coated with the polymer surfactant/human platelet 4 complex, *see* Moghaddam, column 11, lines 56-64. However, this alternative embodiment is not within the scope of the present claims because step (2) of the present claims recites coating sensitized particles with an antigen or antibody, and not coating sensitized particles with a polymer surfactant.

In view of the above discussion, Applicants respectfully submit that Moghaddam fails to describe all of the elements of claim 10 (and claims 11-14, 21-30 which depend therefrom) because not every element in the claims are expressly or inherently described in the single prior art reference. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejection under 35 U.S.C. § 103(a)

Claims 10-14 and 21-30stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Mitsuhiro et al., JP 09-304384, ("Mitsuhiro") in view of Wada et al., WO

2004/092733, ("Wada") or Senn et al., WO 91/10747, ("Senn") each taken separately. This rejection is respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

Legal Standard for Determining Prima Facie Obviousness

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

(a) determining the scope and content of the prior art;

(b) ascertaining the differences between the prior art and the claims in issue;

(c) resolving the level of ordinary skill in the pertinent art; and

(d) evaluating any evidence of secondary considerations.

Graham v. John Deere, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. *See* MPEP 2143.03.

Prima Facie case of Obviousness has not been established

The present invention relates to an agent for inhibiting a decrease in measured values in immunoassays, which decrease is caused by an interfering substance(s), as well as an immunoassay using the same. Mitsuhiro teaches a conjugated diene (co)polymer having sulfonic acid groups and/or sulfonic acid salt groups. Mitsuhiro further teaches that using a conjugated diene (co)polymer, such as 1,3-butadiene, is indispensable.

In contrast, the present invention does not use a conjugated diene (co)polymer. Further, although Mitsuhiro mentions immunoagglutination (only one word), the effectiveness of using the conjugated diene (co)polymer is described only for immunochromatography. Still further,

the effectiveness of using the conjugated diene (co)polymer, even for immunochromatography, is not experimentally shown.

Applicants further submit that Wada relates to a migration shift assay. Wada teaches how to carry out a step of contacting a sample with an affinity molecule to form a complex in the presence of a charged polymer. Following the method of Wada, the formed complex is separated after the step of contacting the sample with the affinity molecule. Thus, following the method of Wada, a separation step is indispensable.

However, Wada does not disclose or suggest an immunoagglutination method. In contrast, the present invention, as amended, is directed to an immunoagglutination method that has no separation step. Although Wada refers to the use of polystyrene latex, the polystyrene latex of Wada is used as a charged carrier molecule. As such, Wada is totally silent about the use of polystyrene latex in an immunoagglutination method.

In addition, Applicants submit that while Senn teaches an immunoassay, Senn is also totally silent about an agglutination immunoassay. Specifically, Senn teaches that the non-specific binding between an HIV envelope protein and cell receptors (CD4) can be decreased by an inhibitor between the HIV envelope protein and CD4. Senn further states that a number of sulfonated polyanions were tested for the ability to inhibit the binding with an anti-CD4 monoclonal antibody.

However, Senn merely mentions a polyanion-biding site, which is closely related to, but is different from the binding region of the HIV envelope protein (gp120). As such, the inhibition of the interaction between HIV envelope protein and CD4 is not disclosed at all. Moreover, even assuming *arguendo* that Senn discloses the inhibition of the binding between CD4 and the HIV envelope protein by the sulfonated polyanion, since CD4 is expressed on the cell surface and CD4 is thought not to exist in the blood serum from which the cells have been removed, there is no experimental data from Senn which shows that the sulfonated polyanion is effective in the detection of an antibody in the blood serum. Therefore, Applicants submit that Senn does not suggest the problem of a decrease in the measured values determined by the latex agglutination method.

In view of the above discussion, Applicants submit that the Examiner has failed to establish that the cited prior art documents would convey to one of skill in the art a reasonable

expectation of success to obtain the presently claimed invention. Accordingly, the combination of the cited references does not render the present invention *prima facie* obvious. Thus, Applicants respectfully request reconsideration and withdrawal of this rejection.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Shawn A. Hamidinia, PhD, Registration No. 58,931, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

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Respectfully submitted,

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